

URGENT FIELD SAFETY NOTICE

This **Field Safety Notice** calls attention to a safety aspect of the Terumo Extracorporeal Tubing Sets involving the LN130B Over-pressure Safety Valve or the LH130 Single, Sterile Over-pressure Safety Valve

Attention: Chief of Perfusion; Director of Operating Room Services; Director of Biomedical Services; Risk Management

Affected Product: LH130 Single, Sterile Over-pressure Safety Valve (often referred to as Vent Valve), LN130B Non-Sterile Over-pressure Safety Valve, Extracorporeal Tubing Set containing the Over-pressure Safety Valve

Reference Number: FSN 1702

Effective Date: July 17, 2017

Action: Advisory



REASON FOR CORRECTION

This Field Safety Notice calls attention to a situation that may arise with the LN130B over-pressure safety valve (OPS valve) within your Terumo Extracorporeal Tubing Set or the LH130 single, sterile OPS valve, and recommends how to check to ensure the duckbill valve within the OPS valve is patent and allows flow through the valve.

The LN130B or LH130 OPS valves are to prevent reversal of blood flow and the prevention of air embolism as well as limit excessive negative and positive pressure in the vent catheter. The OPS valve allows for flow in only one direction (from the catheter in the heart to the cardiotomy reservoir).

Terumo Cardiovascular Systems (Terumo CVS) has received reports of no flow through the OPS valve. Terumo CVS has received no reports of patient injury due to this issue.

WHAT TO DO NEXT

Review this Urgent Field Safety Notice and follow the instructions in the Recommended Action section of this letter.

Note that Terumo CVS is not requesting removal or return of product as a result of this Field Safety Notice activity.

If you have questions, contact your local Terumo representative.

POTENTIAL HAZARD

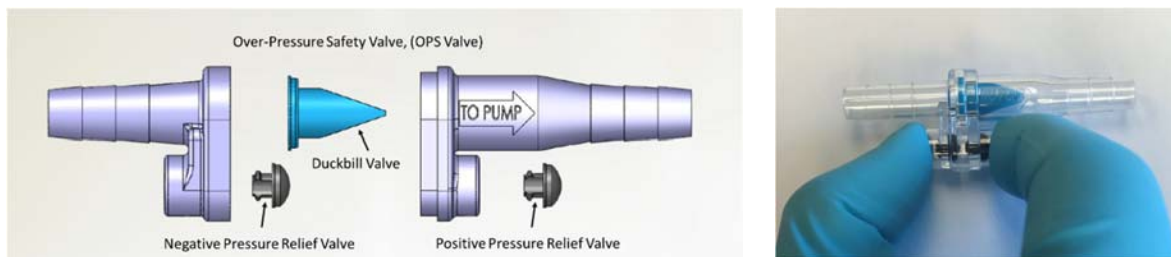
No flow through the duckbill valve within the OPS valve would prevent the ability to vent blood from the left ventricle, potentially resulting in distension of the ventricle. If the distension is prolonged, this may result in severe ventricular dysfunction.

RECOMMENDED ACTIONS

Note: This is an advisory Field Safety Notice. Terumo CVS is not requesting removal or return of product as a result of this activity.

Terumo CVS recommends that the customer test the valve in the tubing pack prior to use to ensure flow through the valve.

1. A member of the surgical team shall place the sterile end of the tubing with LN130B or LH130 OPS valve in a basin of fluid on the sterile field and initiate pump flow to ensure flow through the valve.
2. If no fluid flow is evident through the duckbill valve after the test described above, maintain the tubing in the basin and place gloved fingers over the positive and negative umbrella relief valves (*see diagram below*). Turn on the roller pump at approximately 500 mL/minute and allow up to 30 seconds to create negative pressure on the duckbill valve to initiate fluid flow through the device. Once the duckbill is opened, it will operate as intended. Turn off roller pump.



3. If flow is still not observed, then we recommend removing the valve and replacing it with a single, sterile OPS valve. Please return the defective LN130B or LH130 OPS valve to Terumo.
4. If you do not have a single, sterile OPS valve available, open a new Extracorporeal Tubing Set and use the line and OPS valve from it.

AFFECTED POPULATION

Any patient who is exposed to a Extracorporeal Tubing Set with LN130B OPS valve or a LH130 single, sterile OPS valve.

AFFECTED PRODUCT

Catalog Number	Product Description	Lot Number Range
LH130	Single, Sterile OPS (Vent) Valve	Lot # RK11, RK20, RL02, RL08, RM20, RP08, TE27, TF08, TF14, TF21, TH06, TH16, TL21, TP14, UA11, UC08, UD14, UD28, UE05, UE18, UF09, UG06, UL12, UM10, VA02, VC06
LN130B	Non sterile OPS (Vent) Valve	Lot # RL15, RL22, RM27, RP01, RP22, TA12, TE17, TE20, TE22, TE23, TE24, TE25, TF01, TF04, TF06, TF07, TF08, TF15, TF18, TF19, TF20, TF21, TF30, TG01, TG04, TG05, TG08, TG12, TG15, TG16, TG17, TG19, TG22, TG23, TG24, TG25, TH06, TH07, TH08, TH09, TH10, TH13, TH15, TH17, TH31, TK03, TK04, TK06, TK07, TK10, TK12, TK14, TK17, TK18, TK24, TL23, TL25, TL28, TM01, TM05, TM07, TM09, TM23, TM26, TM28, TN02, TN05, TN19, TN23, TP01, UA04,

		UC01, UC29, UD07, UD21, UD28, UE04, UF23, UF31, UG20, UH18, UK29, UL12, UL19, UL26, UM17, UM24, UN28, UP12, VC13, VD20, VE03, VE24, VF15
CX-AU038X	Extracorporeal Tubing Set	1602458
CX-AU100X	Extracorporeal Tubing Set	1705327
CX-AU101X	Extracorporeal Tubing Set	1608281 till 1608283
CX-AU102X	Extracorporeal Tubing Set	1608111
CX-BE062X	Extracorporeal Tubing Set	1508150 till 1610286
CX-BE063X	Extracorporeal Tubing Set	1509358 till 1701295
CX-BE066X	Extracorporeal Tubing Set	1508106 till 1610150
CX-BE068X	Extracorporeal Tubing Set	1510018 till 1608444
CX-BE069X	Extracorporeal Tubing Set	1509276 till 1704106
CX-BE093X	Extracorporeal Tubing Set	1611202 till 1705265
CX-BE094X	Extracorporeal Tubing Set	1701042
CX-BL040X	Extracorporeal Tubing Set	1606021 till 1606024
CX-BL047X	Extracorporeal Tubing Set	1606124 till 1608137
CX-BL053X	Extracorporeal Tubing Set	1611260 till 1701165
CX-CH034X	Extracorporeal Tubing Set	1510126 till 1512222
CX-CH049X	Extracorporeal Tubing Set	1510305 till 1609149
CX-CH062X	Extracorporeal Tubing Set	1602483 till 1611248
CX-CH071X	Extracorporeal Tubing Set	1603149
CX-CH088X	Extracorporeal Tubing Set	1703348
CX-CH094X	Extracorporeal Tubing Set	1610337 till 1611032
CX-CH096X	Extracorporeal Tubing Set	1610361



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CX-CH102X	Extracorporeal Tubing Set	1701331 till 1705165
CX-CH105X	Extracorporeal Tubing Set	1702330 till 1705169
CX-CR014	Extracorporeal Tubing Set	1609170
CX-CY005	Extracorporeal Tubing Set	1703307 till 1704041
CX-CY006	Extracorporeal Tubing Set	1703312 till 1704046
CX-DB05	Extracorporeal Tubing Set	1601168
CX-DB080	Extracorporeal Tubing Set	1509069 till 1706029
CX-DB317X	Extracorporeal Tubing Set	1702327 till 1702328
CX-DB318	Extracorporeal Tubing Set	1701086
CX-DB319	Extracorporeal Tubing Set	1701088
CX-DB320	Extracorporeal Tubing Set	1701160
CX-DB321	Extracorporeal Tubing Set	1510176 till 1701205
CX-DB329	Extracorporeal Tubing Set	1512152 till 1512153
CX-DB334X	Extracorporeal Tubing Set	1702074
CX-DB351X	Extracorporeal Tubing Set	1606012 till 1609221
CX-DB379X	Extracorporeal Tubing Set	1602431 till 1701337
CX-DB401X	Extracorporeal Tubing Set	1701278
CX-DB407X	Extracorporeal Tubing Set	1705422
CX-DB408X	Extracorporeal Tubing Set	1705420
CX-DB409X	Extracorporeal Tubing Set	1705423
CX-DB421X	Extracorporeal Tubing Set	1606113 till 1607201
CX-DB331X	Extracorporeal Tubing Set	1705419 till 1706076
CX-DB336	Extracorporeal Tubing Set	1510309



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CX-DB337	Extracorporeal Tubing Set	1510310
CX-DB338	Extracorporeal Tubing Set	1510308
CX-DB387X	Extracorporeal Tubing Set	1601152
CX-DB388X	Extracorporeal Tubing Set	1601153
CX-DB404X	Extracorporeal Tubing Set	1603293
CX-DB421X	Extracorporeal Tubing Set	1601420 till 1602345
CX-DB459X	Extracorporeal Tubing Set	1705421
CX-DB462	Extracorporeal Tubing Set	1511160
CX-DB463	Extracorporeal Tubing Set	1511134
CX-DB464	Extracorporeal Tubing Set	1602379 till 1701200
CX-DB466	Extracorporeal Tubing Set	1606002 till 1609285
CX-DB474X	Extracorporeal Tubing Set	1601427
CX-DB475X	Extracorporeal Tubing Set	1601428
CX-DB478	Extracorporeal Tubing Set	1601314
CX-DB481X	Extracorporeal Tubing Set	1605397
CX-DB483X	Extracorporeal Tubing Set	1605396
CX-DB484X	Extracorporeal Tubing Set	1605395
CX-DB497X	Extracorporeal Tubing Set	1603365 till 1705348
CX-DB524	Extracorporeal Tubing Set	1608168 till 1701211
CX-DK043	Extracorporeal Tubing Set	1601107 till 1604027
CX-DK068	Extracorporeal Tubing Set	1508196 till 1704188
CX-DK086	Extracorporeal Tubing Set	1511355
CX-DK087	Extracorporeal Tubing Set	1511071 till 1604034



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CX-DK098	Extracorporeal Tubing Set	1512220 till 1612155
CX-DK099	Extracorporeal Tubing Set	1511487 till 1701364
CX-DK102	Extracorporeal Tubing Set	1608242 till 1706056
CX-DK103	Extracorporeal Tubing Set	1611412
CX-DK107	Extracorporeal Tubing Set	1703066
CX-FAC01	Extracorporeal Tubing Set	1509335 till 1704166
CX-FAC68	Extracorporeal Tubing Set	1607163 till 1702249
CX-FR100	Extracorporeal Tubing Set	1508230 till 1602667
CX-FR169	Extracorporeal Tubing Set	1508297 till 1512178
CX-FR204X	Extracorporeal Tubing Set	1604266 till 1605351
CX-FR221	Extracorporeal Tubing Set	1701207 till 1703013
CX-FR222	Extracorporeal Tubing Set	1606373 till 1704191
CX-GE092X	Extracorporeal Tubing Set	1508121 till 1706139
CX-GE101	Extracorporeal Tubing Set	1508186 till 1702314
CX-GE115X	Extracorporeal Tubing Set	1604265
CX-GE134X	Extracorporeal Tubing Set	1508169 till 1705034
CX-GE136	Extracorporeal Tubing Set	1509208 till 1702335
CX-GE135	Extracorporeal Tubing Set	1508040 till 1703322
CX-GE155	Extracorporeal Tubing Set	1608405
CX-GE157	Extracorporeal Tubing Set	1508156 till 1603133
CX-GE157X	Extracorporeal Tubing Set	1604259 till 1702165
CX-GE166X	Extracorporeal Tubing Set	1508295 till 1704056
CX-GE173X	Extracorporeal Tubing Set	1508077 till 1705329



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CX-GE180	Extracorporeal Tubing Set	1509310 till 1706018
CX-GE181X	Extracorporeal Tubing Set	1601312 till 1705414
CX-GE193	Extracorporeal Tubing Set	1510130 till 1702017
CX-GE195X	Extracorporeal Tubing Set	1509221 till 1704039
CX-GE204X	Extracorporeal Tubing Set	1511060 till 1702010
CX-GE211X	Extracorporeal Tubing Set	1602490 till 1604062
CX-GE216X	Extracorporeal Tubing Set	1607434
CX-GE218	Extracorporeal Tubing Set	1607383 till 1609381
CX-GG005	Extracorporeal Tubing Set	1509148 till 1512015
CX-GG006	Extracorporeal Tubing Set	1509306 till 1608008
CX-GG009	Extracorporeal Tubing Set	1509346 till 1705159
CX-GG012	Extracorporeal Tubing Set	1512016 till 1608235
CX-GG016	Extracorporeal Tubing Set	1511441 till 1703131
CX-GG038	Extracorporeal Tubing Set	1609057 till 1610015
CX-GG039	Extracorporeal Tubing Set	1608244 till 1703189
CX-GG041	Extracorporeal Tubing Set	1703190
CX-GG042	Extracorporeal Tubing Set	1611349
CX-GG045	Extracorporeal Tubing Set	1703354
CX-GG046	Extracorporeal Tubing Set	1703353
CX-IC002	Extracorporeal Tubing Set	1603257
CX-IS019	Extracorporeal Tubing Set	1512012 till 1701174
CX-IS021	Extracorporeal Tubing Set	1512237 till 1701173
CX-IS022	Extracorporeal Tubing Set	1512014 till 1701176



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CX-IS039	Extracorporeal Tubing Set	1511097 till 1511100
CX-IS041	Extracorporeal Tubing Set	1601096 till 1701171
CX-IS055	Extracorporeal Tubing Set	1509228 till 1702053
CX-IS057	Extracorporeal Tubing Set	1603163 till 1609313
CX-IS061	Extracorporeal Tubing Set	1702107
CX-IS062	Extracorporeal Tubing Set	1509019 till 1609087
CX-IS071	Extracorporeal Tubing Set	1602333 till 1701339
CX-IS082	Extracorporeal Tubing Set	1601310 till 1601388
CX-IS083	Extracorporeal Tubing Set	1702196
CX-IS088X	Extracorporeal Tubing Set	1705005
CX-IS089X	Extracorporeal Tubing Set	1705006
CX-IT090X	Extracorporeal Tubing Set	1703262 till 1705334
CX-IT095X	Extracorporeal Tubing Set	1509168 till 1704075
CX-IT096X	Extracorporeal Tubing Set	1509170 till 1705332
CX-IT139X	Extracorporeal Tubing Set	1511211 till 1605168
CX-IT160X	Extracorporeal Tubing Set	1608174 till 1705244
CX-IT223X	Extracorporeal Tubing Set	1508331 till 1705206
CX-IT226X	Extracorporeal Tubing Set	1508266 till 1705288
CX-IT228X	Extracorporeal Tubing Set	1511263 till 1703319
CX-IT246X	Extracorporeal Tubing Set	1509200 till 1704007
CX-IT254X	Extracorporeal Tubing Set	1510282 till 1705293
CX-IT259X	Extracorporeal Tubing Set	1602273 till 1705015
CX-IT290X	Extracorporeal Tubing Set	1606141 till 1705296



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CX-IT291X	Extracorporeal Tubing Set	1703285 till 1705339
CX-IT292X	Extracorporeal Tubing Set	1703288 till 1705340
CX-IT304X	Extracorporeal Tubing Set	1705301
CX-IT304X	Extracorporeal Tubing Set	1611345 till 1705301
CX-IT305X	Extracorporeal Tubing Set	1704136 till 1704137
CX-IT306	Extracorporeal Tubing Set	1702299 till 1705303
CX-IT314X	Extracorporeal Tubing Set	1704132
CX-NG002	Extracorporeal Tubing Set	1608016
CX-PL083	Extracorporeal Tubing Set	1510298 till 1510326
CX-QE12	Extracorporeal Tubing Set	1509183 till 1705051
CX-QE4	Extracorporeal Tubing Set	1510037 till 1702179
CX-ROCA	Extracorporeal Tubing Set	1508281 till 1702151
CX-RU046	Extracorporeal Tubing Set	1511169 till 1705155
CX-RU075	Extracorporeal Tubing Set	1612216
CX-RU100	Extracorporeal Tubing Set	1509214 till 1705025
CX-RU100X	Extracorporeal Tubing Set	1510260 till 1604246
CX-RU101X	Extracorporeal Tubing Set	1508060 till 1705093
CX-RU103	Extracorporeal Tubing Set	1510157 till 1705210
CX-RU103X	Extracorporeal Tubing Set	1509223 till 1702202
CX-RU124	Extracorporeal Tubing Set	1603427 till 1609168
CX-RU125X	Extracorporeal Tubing Set	1603403 till 1705091
CX-SA021X	Extracorporeal Tubing Set	1608332
CX-SA022X	Extracorporeal Tubing Set	1608331



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CX-SA024X	Extracorporeal Tubing Set	1610041
CX-SA030X	Extracorporeal Tubing Set	1612066
CX-SA039X	Extracorporeal Tubing Set	1701222
CX-SE013	Extracorporeal Tubing Set	1605061 till 1609320
CX-SE030	Extracorporeal Tubing Set	1604247
CX-SE037	Extracorporeal Tubing Set	1604248
CX-SL009X	Extracorporeal Tubing Set	1509139 till 1705388
CX-SL017X	Extracorporeal Tubing Set	1604010 till 1702007
CX-SP022	Extracorporeal Tubing Set	1508172 till 1704103
CX-SP034XC	Extracorporeal Tubing Set	1510317 till 1702320
CX-SP049X	Extracorporeal Tubing Set	1509339 till 1704027
CX-SP054A	Extracorporeal Tubing Set	1508191 till 1703103
CX-SP054B	Extracorporeal Tubing Set	1508174 till 1703103
CX-SP064	Extracorporeal Tubing Set	1511077 till 1603308
CX-SP066XA	Extracorporeal Tubing Set	1509260 till 1510314
CX-SP066XB	Extracorporeal Tubing Set	1508036 till 1703211
CX-SP066XC	Extracorporeal Tubing Set	1609116 till 1704028
CX-SP070	Extracorporeal Tubing Set	1508173 till 1704091
CX-SP076A	Extracorporeal Tubing Set	1512235 till 1602425
CX-SP076B	Extracorporeal Tubing Set	1603098 till 1703209
CX-SP079	Extracorporeal Tubing Set	1509038 till 1702160
CX-SP091	Extracorporeal Tubing Set	1510073 till 1608045
CX-SV055	Extracorporeal Tubing Set	1508086 till 1705007



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CX-SV056	Extracorporeal Tubing Set	1509345 till 1603090
CX-SV059	Extracorporeal Tubing Set	1603006 till 1703321
CX-SV065	Extracorporeal Tubing Set	1605189 till 1607372
CX-SV072	Extracorporeal Tubing Set	1705124
CX-SV073	Extracorporeal Tubing Set	1706016 till 1706089
CX-TE014	Extracorporeal Tubing Set	1510047 till 1609305
CX-UK224	Extracorporeal Tubing Set	1509377 till 1703242
CX-UK325	Extracorporeal Tubing Set	1508065 till 1509238
CX-UK343	Extracorporeal Tubing Set	1508113 till 1706274
CX-UK352	Extracorporeal Tubing Set	1702048 till 1704102
CX-UK371	Extracorporeal Tubing Set	1508070 till 1703114
CX-UK437	Extracorporeal Tubing Set	1510161 till 1701045
CX-UK440	Extracorporeal Tubing Set	1605183
CX-UK448	Extracorporeal Tubing Set	1601401 till 1703206
CX-UK460	Extracorporeal Tubing Set	1603084
CX-UK467	Extracorporeal Tubing Set	1604263
CX-UK484	Extracorporeal Tubing Set	1612197 till 1704158
CX-UK486	Extracorporeal Tubing Set	1611187
CX-UK487	Extracorporeal Tubing Set	1701183
CX-UK488	Extracorporeal Tubing Set	1706078

CUSTOMER INSTRUCTIONS

- Review this Field Safety Notice and the Recommended Actions.
- Assure that all users receive notice of this issue.
- Confirm receipt of this Field Safety Notice by emailing or faxing the attached Customer Response Form to the email address or fax number indicated on the form.



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- Test the OPS valve for flow prior to going on cardiopulmonary bypass by using the instructions provided in this letter.
- To return defective OPS valves, follow your complaint reporting protocol and contact Terumo.

QUESTIONS?

We encourage you to contact your local Terumo sales organization with any questions or concerns.

REPORTING

Any adverse event experienced with the use of this product, and/or quality problems shall immediately be reported to your local Terumo sales organization.

We confirm that this *Field Safety Notice* has also been notified to your national Competent Authority.

Organisation (to be completed by the sales or dealer)

Contact name (function)

Contact phone, mobile, email



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FIELD SAFETY NOTICE - CUSTOMER REPLY FORM

Affected Product: LH130 Single, Sterile Over-pressure Safety Valve (often referred to as Vent Valve),
LN130B Non-Sterile Over-pressure Safety Valve,
Extracorporeal Tubing Set containing the Over-pressure Safety Valve

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Action: Advisory

Please complete, sign and e-mail or fax this back:

To:

E-mail/Telefax:

Client number	
Hospital Name	
City	
Country	

Our records indicate that you have received devices from the affected population.

Catalog Number	Product Description	Lot number

By completion and return of this form, I am confirming receipt, reading and acting on this Field Safety Notice.

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1702A [EN]